

### REMARKS

Claims 1, 3-8, 10-21, 24-32 and 34-37 are pending. Claims 1, 3-6, 14, 17, 32, and 33-37 are under examination and claims 7-8, 10-13, 15, 16, 18-21, and 24-31 have been withdrawn from consideration. In the final Office action dated June 21, 2007, no claims were allowed and claims 34-37 were shown as withdrawn from consideration (on PTOL-326 and page 2, paragraph 2) as being drawn to a non-elected invention. Applicants request that dependent claims 34-37 be reconsidered because they depend from claim 32, which is under consideration.

Applicants presented an after final amendment filed on August 21, 2007. An Advisory Office action dated September 18, 2007 was delivered electronically, which stated that the proposed amendments filed in the after final reply would not be entered because they raise new issues that would require further consideration and that they were not deemed to place the application in better form for appeal. The Advisory action further stated that a clause in amended claim 1 raised new issues under 35 U.S.C. 112, first and second paragraph.

Amendments to claims 1, 20, 21, 24 and 32 are presented herein. These amendments respond to the issues raised in the Office action dated June 21, 2007 and the Advisory Office action and do not add new matter because they are based on the original claims and the disclosure, particularly in page 4, line 25 to page 7, line 25, and at page 9, line 27 to page 10, line 16.

### Comments on Advisory Action

With respect to the Advisory action comments in the continuation sheet, which refer to the specification at page 10, Applicants respectfully respond that the term "complementary" has been well known to those of ordinary skill in the art of molecular biology for many years (e.g., Watson, J.D. and Crick, F.H.C., 1953, *Cold Spring Harbor Symposium* 18: 123; Kornberg, A., 1974, *DNA Synthesis*, W.H. Freeman and Company (San Francisco, USA), pages 2, 7-13, 23, 11 and 114). Similarly, the terms "RNA equivalent" and "sequence" are well known terms for those of ordinary skill in the art of molecular biology, biochemistry and chemistry of nucleic acids. Applicants description at page 9, line 27 to page 10, line 20 is consistent with the concepts and general knowledge of persons of ordinary skill in the relevant arts related to complementarity of nucleic acid sequences. Therefore, Applicants are somewhat confused by the comments in the Advisory action that allege that issues under 35 U.S.C. §112, paragraphs 1 and 2 have

been raised by the after final amendments. Applicants believe that amended claims 1 and 32 presented herein fulfill the requirements of 35 U.S.C. §112, paragraphs 1 and 2. If the Examiner disagrees, Applicants respectfully request that the Examiner propose alternative claim language that she would find more acceptable in view of the requirements of 35 U.S.C. §112, paragraphs 1 and 2.

**Claim Rejections under 35 U.S.C. § 102**

The rejection of claims 1 and 32 under 35 U.S.C. § 102(e) based on the disclosure in US patent 6,770,479 (Lee et al.) was maintained because the examiner said that "the claim is drawn to a composition comprising synthetic oligonucleotide -- or a substantially complementary sequence or -----. Therefore, the opposite strand of said sequence is substantially complementary sequence of about 40 nucleotides in a composition would hybridize to the target sequence."

Claims 1 and 32 have been amended to clarify the sequences of the synthetic oligonucleotides encompassed by the compositions of claims 1 and 32. The claimed compositions are oligonucleotides in a specified size range (about 25 to about 40 nt) that hybridize specifically to a sequence contained in a *pagA* target sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or a sequence that is fully complementary to a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or RNA equivalent of a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, or RNA sequence that is fully complementary to a sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24. The claims further specify that at least one synthetic oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and SEQ ID NO:8.

Lee et al. (US Patent No. 6,770,479) disclose a 1,710 nucleotide sequence (SEQ ID NO:4) that contains a subsequence that corresponds to Applicants' target sequences. Whereas Lee et al. disclosed a large sequence that contains many potential subsequences, Applicants selected specific target sequences contained within the larger sequence or its complementary sequence. Applicants' claimed oligonucleotides are identified by size limitations and by hybridizing specifically to target sequences consisting of SEQ ID Nos. 21, 22, 23 or 24, or sequences complementary to a sequence consisting of SEQ ID Nos. 21, 22, 23 or 24, or RNA equivalents of the sequences described in the previous two clauses. Lee et al.'s 1,710

nucleotide sequence does not fall in the size range of the claimed oligonucleotides, and therefore does not disclose every element of the claimed compositions. A person of ordinary skill in the art of molecular biology or nucleic acid biochemistry would not consider Lee et al.'s disclosure of a 1,710 nucleotide sequence to be identical to the claimed invention. Because of the differences between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention, Applicants' respectfully submit that Lee et al. does not anticipate the claimed compositions.

Applicants request consideration of amended claims 1 and 32 in view of these comments and seek allowance of amended claims 1 and 32.

#### **Rejections under 35 U.S.C. § 112, first paragraph**

The rejection of claims 1 and 32 under 35 U.S.C. § 112, first paragraph was maintained for reasons forth in the Office action dated December 27, 2006, based on the use of "substantially complementary" because the Examiner alleged that the claims could include "a substantial number of species which lack significant/sufficient complementarity to SEQ ID NO:21/22/23/24."

Applicants maintain that a person of ordinary skill in the art of molecular biology would be able to perform mere routine testing based on the high level of skill of a molecular biologist, the guidance in the specification, and the state of the prior art related to nucleic acid hybridization to assess the performance of synthetic oligonucleotides and determine their characteristics in view of Applicants' disclosure, including working examples. That is, a person of ordinary skill in the art of molecular biology would merely perform what that skilled molecular biologist would regard as routine testing based on known parameters to determine if sequences fall within the scope of the claimed invention and the molecular biologist of ordinary skill would not consider such routine testing to be undue experimentation.

Claims 1 and 32 have been amended herein. Applicants believe these amendments are fully responsive to the rejections and fulfill the requirements of 35 U.S.C. § 112, first paragraph. Applicants refer the Examiner to the comments on the Advisory action presented above for additional information related to this rejection. In view of the comments and amendments presented herein, Applicants request allowance of claims 1 and 32.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1, 3-6, 14, 17 and 32 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite because claims 1 and 32 recite "substantially complementary."

Applicants have amended claims 1 and 32 in a way that they believe is fully responsive to the rejections under § 112, second paragraph. Applicants respectfully refer the Examiner to the comments on the Advisory action which are also related to these rejections. Applicants respectfully submit that the amended claims 1 and 32 fulfill the requirements of § 112, second paragraph. Therefore, Applicants request allowance of claims 1 and 32 and dependent claims 3-6, 14, and 17. Applicants also remind the Examiner that claims 34 to 37 depend from claim 32.

**Rejoinder of Withdrawn Claims**

Applicants responded with traverse to the restriction requirement mailed March 2, 2006, that divided the claims of the application into five groups. Applicants elected composition claims (original claims 1-6, 14, 17, 32 and 33) drawn to oligonucleotides that hybridize specifically to the *pagA* target sequence.

Applicants believe that the amendments presented herein to claims 1 and 32 place the elected claims in condition for allowance. Applicants, therefore, request allowance of the elected independent composition claims 1 and 32 and all pending claims that depend from them.

Applicants have amended the withdrawn independent method claim to include all the limitations of the independent product claims. More specifically, claim 20 has been amended: (1) in the second providing step to delete reference to the probes specific for a *capB* target sequence in a pXO1 plasmid and to amend the references to probes specific for the *pagA* target sequences using language as in amended claims 1 and 32; (2) in the hybridizing step to delete references to the probes specific for a *capB* target sequence; and (3) in the detecting step to delete reference to the *capB* target sequence. By these amendments, Applicants respectfully submit that the independent method claim complies with the requirements for rejoinder as described in the restriction requirement. Applicants, therefore, request rejoinder of claim 20 and allowance of the independent method claim and all pending claims that depend from it.

Applicants have amended withdrawn dependent claim 21 to insert the references to the *capB* probes and target sequence, using the language of original claim 20, to describe the elements that the method further comprises by this dependent claim. Withdrawn dependent claim 24 has also been amended to make it dependent on amended claim 21 and to use more concise language consistent with the amendments to claim 21.

The Examiner stated in the Office action dated June 21, 2007 that a complete reply must include cancellation of nonelected claims or other appropriate action under 37 C.F.R. 1.144. In this RCE application, Applicants request reconsideration of the withdrawn claims and rejoinder of the method claims if allowable subject matter is found in the product claims. Applicants also request rejoinder of the dependent claims for both the product claims and method claims, which may add limitations related to *capB* or other sequence, because if the independent product and process claims 1, 20 and 32 are found allowable, then the dependent claims that define additional limitations should also be allowable. Pending composition claims 3-8 and 10-19 all depend ultimately from independent claim 1. Pending composition claims 34-37 all depend from independent claim 32. Pending method claims 21 and 24-31 all depend ultimately from amended independent claim 20. Hence, Applicants request reconsideration and allowance of all of the pending claims if amended claims 1, 20 and 32 are found allowable.

#### Conclusion

Applicants respectfully submit that this submission is fully responsive to the last Office action issued in this application and that the claims, as amended, are in condition for allowance. Accordingly, withdrawal of the rejections and allowance of the application is earnestly solicited. The undersigned has made a good-faith effort to address all the points raised in the Office actions, including the Advisory action, and to place the claims in condition for allowance. If minor matters remain, however, the Examiner is invited to contact the undersigned at the telephone number below.

Serial No. 10/712,654  
Filed: November 12, 2003  
RCE filed: October 19, 2007  
Art Unit: 1645

AMENDMENT filed with REQUEST FOR CONTINUED EXAMINATION  
Atty. Docket No. GP141-03.UT  
Confirmation No. 8961

Page 14

Fee Authorization

Authorization is hereby provided to debit any fees associated with this filing and all filings accompanying the Request for Continued Examination for this application from the USPTO deposit account number No. 07-0835 maintained by Gen-Probe Incorporated.

Certification of Transmission

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being filed electronically, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Respectfully submitted,

Date: October 19, 2007

By:

  
Christine A. Gritzmecher

Reg. No. 40,627

GEN-PROBE INCORPORATED

10210 Genetic Center Drive

San Diego, California 92121

Tel.: (858) 410-8926 FAX: (858) 410-8928